DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2014

Spacelabs Healthcare
c/o Mr. Thomas Kroenke
Speed To Market, Inc.
PO Box 3018
Nederland, CO 80466

Re: K141113
Trade/Device Name: Ontrak (90227) Ambulatory Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: System, Measurement, Blood-pressure, Non-Invasive
Regulatory Class: Class II
Product Code: DXN
Dated: August 26, 2014
Received: August 28, 2014

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141113

Device Name

Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure (ABP) Monitor

Indications for Use *(Describe)*

The Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure (ABP) Monitor is a small, lightweight unit designed to take blood pressure and heart rate measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number:	K141113
Submission Date:	26 September 2014
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court John Tate Road Hertford SG13 7NW United Kingdom
Submitter Contact:	Spacelabs Healthcare 35301 SE Center St Snoqualmie, WA 98065 Mr. Al Van Houdt Spacelabs Healthcare Phone: +1 (425) 363- 5970 Fax: +1 (425) 363-5762 Email: al.vanhoudt@spacelabs.com
Application Correspondent:	Thomas Kroenke Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Healthcare 35301 SE Center St Snoqualmie, WA 98065 and/or Spacelabs Healthcare Medical Equipment (SUZHOU) Co., Ltd. Building 30, West Wing ChuangTou Industrial Square Yang Xian Road, SIP Suzhou, Jiangsu, China 215122
Trade Name:	Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure Monitor
Classification Name:	System, Measurement, Blood-pressure, Non-Invasive
Classification Regulation:	21 CFR §870.1130
Product Code:	DXN

510(k) Summary

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure Monitor	K103732	Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor

Device Description:

The Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure (ABP) Monitor (Spacelabs OnTrak) is a small, lightweight unit designed to take non-invasive blood pressure (NIBP) and heart rate (HR) measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

The Spacelabs OnTrak does not have any physiological alarms, but does have an audible low battery indicator. The Spacelabs OnTrak utilizes the same NIBP cuffs as the predicate device.

Intended Use:

The Spacelabs Model OnTrak (90227) Ambulatory Blood Pressure (ABP) Monitor is a small, lightweight unit designed to take blood pressure and heart rate measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

Technology Comparison:

The Spacelabs OnTrak employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Measurement Method	Oscillometric	Same
Measurement Mode	Automatic or Manual	Same
Measurement Time	Typically 35 to 50 seconds	Same
Systolic Pressure Range	60 to 260 mmHg	Same
Diastolic Pressure Range	30 to 200 mmHg	Same
Manometer Accuracy	0 - 260 mmHg: ± 2 mmHg ± 1 digit 260 - 300 mmHg: ± 3 mmHg ± 1 digit	0 - 300 mmHg: ± 3 mmHg or 2 %, whichever is greater
Maximum Cuff Pressure in normal operation	270 mmHg	Same

510(k) Summary

Summary of Performance Testing:

Software

The Spacelabs OnTrak software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicate that the Spacelabs OnTrak software complies with its predetermined specifications and the applicable standards and guidance documents.

Electrical Safety

The Spacelabs OnTrak was tested for performance in accordance with the following standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1. General requirements for basic safety and essential performance.*
- *UL 60601-1: 2006, Medical electrical equipment, Part 1: Particular requirements for safety.*

Test results indicate that the Spacelabs OnTrak complies with its predetermined specifications and the applicable standards.

Electromagnetic Compatibility

The Spacelabs OnTrak was tested for performance in accordance with internal requirements and the following standards:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicate that the Spacelabs OnTrak complies with its predetermined specifications and the applicable standards.

510(k) Summary

Performance Testing – Bench

The Spacelabs OnTrak was tested for performance in accordance with internal requirements and the following standards:

- *IEC 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.*
- *IEC 60601-1-11: 2010, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *IEC 80601-2-30: 2009, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.*
- *ISO 81060-2: 2009, Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type.*

Test results indicate that the Spacelabs OnTrak complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Spacelabs OnTrak. The results of these activities demonstrate that the Spacelabs OnTrak is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the Spacelabs OnTrak is considered substantially equivalent to the predicate device.